EXHIBIT A

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431 South 7th Street, Suite 2500
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Re: Bair Hugger Forced Air Warming Product Liability

Dear Ms. Lewis,

Per your request, I have reviewed materials relating to the Bair Hugger Forced Air Warming Product Liability lawsuit and provide the following opinions.

Professional background and experience

I completed my residency training in anesthesiology in 1984 and practiced continuously until 2017, practicing for 26 years at Newton-Wellesley Hospital in Newton, MA. I have been continuously licensed in Massachusetts since 1980. I have been certified by the American Board of Anesthesiology since 1984 and currently hold the position of Clinical Professor of Anesthesiology at Tufts University School of Medicine. I am a faculty member in Safe Surgery program of Ariadne Labs, a health systems innovation center at the Harvard T.H. Chan School of Public Health and Brigham & Women's Hospital. I served as an examiner for the American Board of Anesthesiology from 2000-2015. I have held numerous positions in the American Society of Anesthesiologists including its presidency in 2010 and, most recently, as its Chief Quality Officer. During the years prior, I had responsibility for the Society's work in the area of professional standards, performance measurement, patient safety and other related areas. Consequently, I participated as chair of the American Medical Association's Physician Consortium for Performance Improvement workgroup developing performance measures in anesthesiology and critical care in 2007 and again when the group reconvened in 2012. Among the measures developed was one addressing perioperative temperature management that was subsequently adopted by Medicare's Physician Quality Reporting System and endorsed by the National Quality Forum. This measure was chosen because of the recognized practice gap in effective intraoperative temperature management and the resulting preventable morbidity. My experience and education is more fully set forth in my Curriculum Vitae, attached hereto as Exhibit A.

Over these 30+ years, my practice consistently included administering anesthesia for major orthopedic surgery. I have provided anesthesia for more than 400 total joint replacement operations. For the more than twenty years since we have had access to Bair Hugger forced air warming technology, I have applied it in virtually every hip or knee replacement and I understand it to be widely chosen by anesthesiologists nationwide. The use of forced air warming has provided patient comfort and reduced postoperative shivering, a side effect that is very unpleasant for patients in addition to reducing the risk of cardiovascular and bleeding complications. I have found forced air warming to be safe, easy to use, and effective at maintaining patients' normal temperatures. In addition, it has been part of my strategy to reduce the likelihood of surgical site infection in my practice at Newton-Wellesley Hospital which exclusively uses Bair Huggers for intraoperative patient warming. In recent years, the rate of infection in our institution has been 0.6%, approximately half the prevailing national infection rate.

Materials reviewed.

In preparing my opinions, I have considered the literature and discovery material pertinent to this case listed in Exhibit B.

I may use all or parts of these materials, or summaries and depictions thereof, as exhibits or demonstrative aids to summarize or support my opinions.

<u>Opinions</u>

The below opinions are given to a reasonable degree of medical and scientific certainty. They are based upon my education, training, experience, and knowledge of the literature, as well as the above list of materials reviewed.

Optimal patient care in arthroplasty surgery includes forced air warming.

Hypothermia poses many risks to surgical patients, including and especially an increased risk of surgical site infection in arthroplasty patients. The most effective method of reducing these risks is through the use of forced air warming. This practice is endorsed by multiple independent and highly respected groups worldwide including: ECRI Institute[1], AMA Physician Consortium for Performance Improvement, US Centers for Medicare & Medicaid Services[2], American Society of Perianesthesia Nurses[3], the UK National Institute for Clinical Excellence (NICE)[4] as well as the leading US textbook of anesthesiology, Miller's Anesthesia[5]. These sources recommend not only patient warming, but specifically recommend the use of forced air warming to maintain normothermia. The landmark study[6] demonstrating that prevention of hypothermia reduced the risk of surgical site infection notably used forced air patient warming to achieve normothermia and the associated reduction in wound infection rate. While Kurz does not directly address hip and knee arthroplasty, the results should guide management of arthroplasty cases because the known physiologic effect of hypothermia impairing peripheral

circulation gives the findings face validity. Host defenses against microbial infection depend on delivery of oxygen and leukocytes to the surgical wound through adequate microcirculation. In this sense, hip and knee replacements are much more similar to colectomy than they are different.

In my clinical practice, the decision to universally employ forced air warming in my arthroplasty patients is guided by the above sources and other relevant literature, awareness of peer group practice, the evidence of efficacy from the literature[7,8,9,10] and from my personal clinical experience. The Bair Hugger is a safe and efficacious device.

Clinical tactics to mitigate the risk of surgical infection

Controlling the risk of infection is a multidisciplinary collaboration involving all operating room personnel. The anesthesiologist influences a number of factors known to impact the frequency of surgical infections. In addition to maintaining normothermia, the anesthesiologist must make every effort to avoid hyperglycemia and to administer appropriate antibiotic prophylaxis in a timely fashion. The team's adherence to sterile operating room technique, surgical tissue handling, duration, cleanliness and sterility of surgical instruments and implants are among the many factors underlying the extent of wound contamination which to a greater or lesser degree is inevitable, occurring as frequently as 89% in cardiac surgical procedures[11] and 30% in clean orthopedic surgery[12]. The counterbalancing factors influencing the development of a clinically significant wound infection relate to patient defense factors. Major considerations in determining the efficacy of these factors include the integrity of the circulation delivering oxygen and white blood cells to the tissues in the surgical wound. Many patient co-existing conditions are known to impair these defenses, as are acute perturbations in patient physiology occurring during surgery and anesthesia, notably including hypothermia. Minimizing these disturbances is the goal of intraoperative patient management.

Theoretical concerns about forced air warming disrupting laminar flow are irrelevant and based on invalid experimental models.

The benefits of operating room laminar flow ventilating systems remain difficult to demonstrate and these costly systems are now rarely installed in new operating rooms. The best controlled and most influential study on this question, including more than 99,000 operations, concluded in 2008 that "OR ventilation with laminar airflow showed no benefit and was even associated with a significantly higher risk for severe SSI after hip prosthesis.[13]" The American Society of Anesthesiologists OR Design Manual states: "Careful mathematical analyses of airflow suggest laminar airflow is not necessary when the previously noted recommendations are met. Clinical studies are confirmatory.[14]" Thus, a conclusion that interference with an air handling technology that does not clearly reduce infection risk cannot logically imply that this putative interference, if it were demonstrated in a valid experimental model, results in an elevated infection risk.

Despite weak evidence for its benefit, lower extremity arthroplasty surgery may be performed in a laminar air flow environment. Proper use of laminar flow systems requires that only essential personnel and equipment be located in the laminar flow area, often indicated by floor markings or plexiglass overhead curtains. For this reason, anesthesia equipment, including the Bair Hugger, anesthesia machine and monitors and anesthesia personnel are located outside the laminar flow area. It is not feasible to locate the large, unsterile surgical lights outside of the laminar flow area and these inevitably sit directly between the origin of the laminar air flow and the surgical incision. In addition, the patient's head and often arms are situated outside the laminar flow area, particularly during lower extremity surgery, because anesthesia providers will have frequent need to access these areas. Since the Bair Hugger upper body warming blanket is tightly secured to the patient's skin at its distal end (usually mid-thorax) with an adhesive strip, is wrapped around the patient's arms, and is further covered by multiple layers of adhesive sterile surgical drapes excluding the blanket from the vicinity of the surgical wound, the main area of egress of hot air is around the head and neck where the blanket is loosely applied. This results in any hot air escaping both far from the surgical wound and outside the laminar flow environment. Thus, alleged effects of the Bair Hugger on laminar flow in the experimental environment are largely irrelevant to actual clinical practice. The opinions of plaintiffs' experts Drs. Stonnington and Jarvis largely rely on this entirely unproven relationship. In addition, these experts also attribute the alleged risk of the Bair Hugger device to the bacterial content of the internal and external surfaces of the device and the output of the Bair Hugger hose. Virtually all of the devices and surfaces in an operating room, except those in the surgical field, are non-sterile and the Bair Hugger hose is never delivering air directly to the patient without a blanket. Based on a frequently cited study, the air emitted from the Bair Hugger blanket does not produce bacterial growth when cultured.[15] This finding – negative cultures of Bair Hugger blanket air flow – also discredits allegations of the inadequacy of air filtration in the Bair Hugger. For these reasons, I disagree with the opinions of Drs. Stonnington and Jarvis on the Bair Hugger causing a risk of surgical site infection because the foundation of those opinions is defective.

The sole study cited by plaintiffs to relate clinical infection to Bair Hugger use relies on an experimental model used to demonstrate disrupted laminar flow that is inherently flawed. Body heat emanating from surgical staff, the effect of the constant movement of 3-4 scrubbed individuals, movement of instruments in the laminar flow environment all can be expected to have an influence on the flow of air around the patient's surgical wound; these accurately describe the actual environment in which total joint replacement procedures are performed. So, a model such as used by McGovern et al[16] to demonstrate this phenomenon that has one individual at the surgical site "motionless" is highly unrealistic, excludes important influences on air movement and cannot form the basis for any conclusion about either laminar flow or surgical infection risk. McGovern's conclusions are also invalid because of other, highly relevant contemporaneous changes in infection prevention practices during the study period. Indeed, McGovern concedes that his

"study does not establish a causal basis" for an alleged association between the Bair Hugger and surgical site infections.

Impartial and authoritative review of warming technology supports the safety of forced air warming.

Clinicians rely on impartial and expert review of the available science to guide clinical decision making. After undertaking a comprehensive and exhaustive review of the available evidence specifically on the question of whether hot air warming devices pose an infection risk, the ECRI concluded in 2013 that they did not.[1] ECRI is a formally designated Evidence-Based Practice Center of the U.S. Agency for Healthcare Research and Quality, established more than forty years ago. More than 5,000 public and private institutions rely on ECRI for evidence reports and assessments of health care technology. Similarly, the National Institutes of Health concludes that "forced-air warming technology does not increase the risk of surgical wound infection.[17]" In 2013, the International Orthopedic Consensus Meeting on Periprosthetic Joint Infection also concluded – by a nearly unanimous vote - that there was no evidence linking forced air warming with an increased incidence of surgical infections in joint replacement surgery.[18] In the same year, the Association of PeriOperative Registered Nurses (AORN) stated in its evidence-based practice recommendations "Forced air warming is safe and the most widely used skin surface warming method…Forced air warming does not increase the risk of wound contamination.[19]"

Notably, during the nearly ten years of their campaign focused on discrediting forced air warming, organizations linked to Hot Dog warming systems, such as heat-rises.blogspot, Orthopedic Infection Advisory and Stop Surgical Infections.org have not produced or disseminated a single credible study associating forced air warming with an increased frequency of clinical wound infection in any setting, relying instead on broadcasting studies on speculative, surrogate measures relating to particles, air flow and parameters other than clinically relevant events.

Cardiovascular heater-cooler device issues are not relevant to forced air warming technology.

Plaintiffs' experts refer to a 2016 FDA Safety Communication[20] addressing a risk of nontuberculous mycobacterial infection in cardiac surgery patients reportedly tracked to a water heater-cooler device used in conjunction with cardiopulmonary bypass circuits. The incidents involve the product of a single manufacturer whose production line reportedly contaminated the heater-cooler pumps before they left the factory. The vector of patient infection was *water vapor* carrying the bacteria and spread in the operating room by the device's fan. Thus, it was not the air from the device but the water vapor it carried that led to the infections. The FDA describes the mechanism of contamination by saying: "Although the water in the circuits does not come into direct contact with the patient, there is the potential for *contaminated water to enter other parts of the device and aerosolize*, transmitting

bacteria through the air and through the device's exhaust vent into the environment and to the patient."

In addition, this was a time-limited problem and the FDA states it is unaware of any similar infections associated with devices manufactured after 2014.
Forced air warming devices do not contain or circulate any water and thus are not susceptible to the problem described in this FDA Safety Communication. There is no history of device contamination during manufacture of the Bair Hugger as was the case with the cardiovascular heater-coolers.

The Bair Hugger's labeling and design were reasonable

From the perspective of an anesthesiologist, the warnings and labeling for the Bair Hugger and its blankets are clear and easily understood, and include instructions regarding the setup of the device and blanket. For the reasons discussed above, the labeling appropriately did not include warnings regarding a risk of infection being caused by the use of the Bair Hugger, for which there is no credible evidence. The diligence of the manufacturer in reliably and aggressively warning clinicians of legitimate device hazards is amply demonstrated by the highly visible and effective campaign to warn against improper use of the device without a warming blanket, known as "hosing[21]" in which the Bair Hugger hose is improperly applied directly to the patient possibly resulting in thermal injury.

Conclusions

- The evidence that maintaining normothermia improves outcomes in surgical patients is firmly established, and this improvement includes a reduction in the risk of surgical site infection.

- Forced air warming devices, in particular the Bair Hugger, have a compelling body of evidence to support their safety and efficacy [7,8,9,10]. Additionally, the Bair Hugger labeling is reasonable and did not need to include a warning of an alleged risk of surgical site infections.

- For these reasons, the practice of using forced air warming in surgical patient care is endorsed by numerous impartial and objective groups that have scrutinized the available evidence. These endorsements establish a standard of care in anesthesia and surgical practice.

- According to the literature and my personal experience, the Bair Hugger does not cause surgical site infections. I am not aware of a single credible scientific study causally linking the use of the Bair Hugger to an increased risk of surgical site infections.

- The studies that address disruptions in laminar flow or increased airborne particle counts do not demonstrate an increased frequency of clinical infection. The only study[16] that is cited to demonstrate this risk is severely limited and its own authors, with a disclosed financial interest in the subject, disavow drawing such a conclusion from their work: "This study does not establish a causal basis for this association. Although the demographics were similar between the patient groups in terms of risk factors for infection, the data are observational and may be confounded by other infection control measures instituted by the hospital…In addition, we were unable to consider all factors that have been associated with SSI…" Thus, there is no study demonstrating a causal relationship between forced air warming technology and surgical site infections.

This report is not meant to be an exhaustive recitation of all of my opinions. I reserve the right to amend and supplement the opinions expressed in this report. I also reserve the right to respond to and rebut all information provided in discovery, which I understand is ongoing, specifically including any opinions offered by Plaintiffs' experts at their depositions or at trial.

Fees

My fees for medicolegal consulting are $500 per hour for document review and reports; for appearances at deposition or trial locally, $2000 for the first hour and $200 each subsequent hour; for appearances at deposition or trial more than 100 miles from Wellesley MA, $3000 for the first hour and $200 each subsequent hour.

Prior Testimony

I have testified at a deposition on March 10, 2014 in Cohen vs Saint Francis Hospital (Superior Court of Hartford CT) and on no other occasion in the past four years.

Alexander A. Hannenberg, M.D.

[1] ECRI Institute. Forced-air warming and surgical site infections. *Health Devices*. 2013; 122-125

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[3] Hooper VD et al. ASPAN's Evidence-Based Clinical Practice Guideline for the Promotion of Perioperative Normothermia: Second Edition. J PeriAnesthesia Nursing 2010 (25) 346-364

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[8] Giesbrecht GG, et al. Comparison of forced-air patient warming systems for perioperative use. *Anesthesiology*. 1994; 80:671-679.

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[15] Avidan MS, Jones N, Ing R et al. Convection warmers – not just hot air. Anaesthesia 2997 (52) 1073-1076

[16] McGovern PD, et al. Forced-air warming and ultra-clean ventilation do not mix. *J Bone Joint Surg Br.* 2011; 93-B:1537-44

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[19] Association of Perioperative Registered Nurses, "Perioperative Standards and Recommended Practices 2013"

[20] UPDATE: Mycobacterium chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T Heater-Cooler System: FDA Safety Communication https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm520191.htm. Accessed 5/19/17

[21] http://safepatientwarming.com/spw/hosingreusecommingling/hosing/index.html. Accessed 5/19/17